

### **BASIS FOR AMENDMENTS**

Claims 1, 2, 5, and 6 were amended to correct certain typographical and clerical errors.

Claim 2 has also been amended to place the claim in independent form by incorporating all of the limitations of the claim from which it depended. In addition, claim 2 has been amended to recite a functional activity for the protein encoded by the OCIF gene. This amendment is supported in the specification at page 4, lines 4-6.

Claim 5 has also been amended to specify that the claimed isolated protein has a molecular weight of about 60 KD determined by SDS-PAGE under reducing conditions. This amendment is supported in the specification at page 5, lines 5-8.

Claim 6 has been amended to recite additional steps in producing the claimed protein. These amendments are supported at page 4, line 23, through page 5, line 5.

No new matter has been introduced by these amendments.

### **REMARKS**

Claim 1, 2, 5, and 6 are pending in this application. In the Office Action mailed on June 23, 1999, the Examiner objected to claim 2 as being of improper dependant form, and rejected claims 1, 2, and 5 under 35 U.S.C. § 101, claim 6 under 35 U.S.C. § 112, first paragraph, and claims 2, 5, and 6 under 35 U.S.C. § 112, second paragraph.

#### ***1. The Objection***

Claim 2 was objected to as being of improper dependent form. Applicants have amended claim 2 to place it in independent form, as suggested by the Examiner. As such, Applicants respectfully request reconsideration and withdrawal of the objection.

**2. *The Rejection Under 35 U.S.C § 101***

Claims 1, 2, and 5 were rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Applicants have amended the claims to recite an isolated DNA molecule or protein, as suggested by the Examiner. Thus, Applications respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 101.

**3. *The Rejection Under 35 U.S.C § 112, First Paragraph***

Claim 6 was rejected under 35 U.S.C. § 112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make or use the invention. Specifically, the Examiner stated that neither SEQ ID NO:1, nor SEQ ID NO:2, encode the complete amino acid sequence of SEQ ID NO:3. Applicants respectfully submit that claim 6, as amended, recites a DNA molecule having a nucleotide sequence comprising SEQ ID NO:1 and SEQ ID NO:2. As can be determined from the sequence listing, the sequences from SEQ ID NOs:1 and 2 encode all five exons of the OCIF of SEQ ID NO:3. As such, Applicants respectfully request that the rejection under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

**4. *The Rejection Under 35 U.S.C § 112, Second Paragraph***

Claims 2, 5, and 6 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Specifically, the Examiner stated that claim 2 was indefinite for limiting a DNA sequence to a genus of DNA molecules. In addition, the Examiner stated that claim 2 was indefinite because it recites the term "OCIF gene," and that an artisan would not be able to determine what additional or material functional limitations were placed upon the claim by this recitation.

Applicants have amended claim 2 to more clearly refer to a DNA molecule. In addition, Applicants have amended claim 2 to further identify an OCIF gene. Specifically, claim 2, as amended, recites specific residues of SEQ. ID NOs:1 and 2, and further recites that the OCIF gene encodes a protein that inhibits differentiation or maturation of osteoclasts. Applicants respectfully submit that claim 2, as amended, provides the artisan with the functional limitations placed upon the claim by the recitation of the "OCIF gene."

In addition, the Examiner stated that claim 5 was indefinite because the molecular weight of a protein varies with the method of determination. Applicants have amended claim 5 to recite that the claimed protein has a molecular weight of about 60 KD determined by SDS-PAGE under reducing conditions.

The Examiner also stated that claim 6 was indefinite because it recited an "express vector," and that there was insufficient antecedent basis for the recitation of "the expression vector." Applicants have amended claim 6 to refer to an "expression vector" rather than an "express vector."

The Examiner also stated that claim 6 was incomplete because it omitted essential steps. Applicants have amended claim 6 to recite the steps of transforming a host cell and culturing the host cell, as suggested by the Examiner.

Finally, the Examiner stated that claim 6 was indefinite because it lacked a process step which related back to the claim preamble and that it was unclear what process was to be achieved. Applicants have amended claim 6 to recite that the protein is expressed in culture and isolated therefrom, as suggested by the Examiner.

Applicants respectfully submit that all of the Examiner's concerns under 35 U.S.C. § 112, second paragraph, have been addressed. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Applicant: Nakagawa et al.  
U.S.S.N.: 09/051,670  
Filed: 8/19/97  
Page: 6

### Conclusion

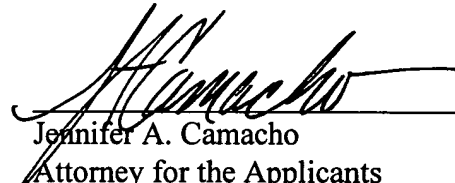
Applicants respectfully submit that the claims are now in condition for allowance. If the Examiner believes that a conversation with Applicants' attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at the telephone number below.

Respectfully submitted,

Date: 9/16/99  
Reg. No. 43,526

Tel. No. (617) 248-7476  
Fax: (617) 248-7100

479JAC3999/66.856561-1

  
Jennifer A. Camacho  
Attorney for the Applicants  
Testa, Hurwitz, & Thibault, LLP  
High Street Tower  
125 High Street  
Boston, Massachusetts 02110